

FEB 06 2002

K013781

## ATTACHMENT H

## SUMMARY OF SAFETY &amp; EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Mitek Products is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Mitek Products choose to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the proposed RigidFix™ 2.7mm BTB Cross Pin Kit is as follows:

**Trade Name:** RigidFix™ 2.7mm BTB Cross Pin Kit

**Sponsor:** Mitek Products  
249 Vanderbilt Avenue  
Norwood, MA 02062  
Registration: 1221934

**Device Generic Name:** Appliance for reconstruction of bone to soft tissue

**Classification:** According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

**Predicate Devices:** Mitek - RigidFix™ 2.7mm BTB Cross Pin Kit (K974291)  
Linvatec BioScrew® Absorbable Interference Screw (K973758)

All of the devices mentioned above have been determined substantially equivalent by FDA.

**Device Description:** The device described in this 510(k) is a sterile, disposable, device designed for single patient use only. The cross pins are constructed of bioabsorbable Poly Lactic Acid (PLA).

**Indications for Use:** The RigidFix™ 2.7mm BTB Cross Pin Kit is indicated for femoral and tibial fixation of autograft or allograft ACL bone-tendon-bone (BTB) grafts.

**Safety and Performance:** Functional and integrity bench testing and Biocompatibility testing (according to the FDA guidance document, ODE Blue Book Memorandum #G95-1, 1995, Use of International Standard ISO-10933, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing") were performed, and the data supported the substantial equivalence of the proposed RigidFix™ 2.7mm BTB Cross Pin Kit. Specifically, testing was performed to determine the initial fixation strength of the proposed RigidFix™ 2.7mm BTB Cross Pin Kit when used for Bone-Tendon-Bone grafted ACL Reconstructions.

**Conclusion:** Based on the Indications for Use, design, technological characteristics and safety and performance testing, the proposed RigidFix™ 2.7mm BTB Cross Pin Kit has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 06 2002

Ms. Jennifer Johnson  
Regulatory Affairs Associate  
Mitek Products  
Ethicon, Inc., a Johnson & Johnson Company  
249 Vanderbilt Avenue  
Norwood, Massachusetts 02062

Re: K013781

Trade Name: Rigidfix™ 2.7mm BTB Cross Pin Kit

Regulation Number: 888.3030

Regulatory Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: II

Product Code: HTY, MAI

Dated: November 13, 2001

Received: November 14, 2001

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

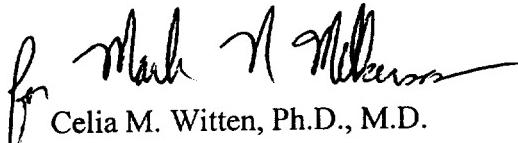
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 – Ms. Jennifer Johnson

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**FEB 06 2002**Page 1 of 1510(k) Number (if known): 013781Device Name: Rigidfix(tm) 2.7mm BTB Cross Pin Kit

Indications for Use: The Mitek RigidFix 2.7mm BTB Cross Pin Kit is indicated for femoral and tibial fixation of autograft or allograft ACL bone-tendon-bone grafts.

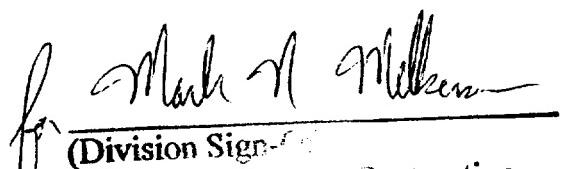
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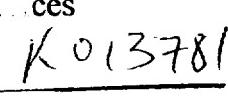
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_

  
f. Mark A. Miller  
(Division Signer)  
Division of General Restorative  
and Neurological Devices

  
K. 013781  
510(k) Number 013781